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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/347,175	07/01/99	HOGLE J	HU98-02PA

EXAMINER	
ZEMAN,R	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/347,175	Applicant(s) HOGLE ET AL.	
	Examiner Robert A Zeman	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *7-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed on 4-16-2001 is acknowledged. Claims 11, 12 and 17 have been amended.

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 13 is acknowledged. The traversal is on the ground(s) that:

1. Groups 1, 2 and 26-48 are closely related in subject matter.

2. Claims 1 and 7-10 are a combination /subcombination which lacks two-way distinctness.

3. The peptide claim 18 differs from HDAg of claim 1 by only a single residue.

4. Claims 1 and 19 are a combination/subcombination.

5. Claims 16, 17, 20 and 21 are directed to compounds within Markush groups with common utility and a common structural feature responsible for the utility.

6. The compounds of Groups 26-31 all share a common utility.

7. The compounds of Groups 38-47 all share a common utility.

8. The 6 sequences in Groups 26-31 and the 11 sequences in Groups 33-47 should be recombined (or be made an election of species) since the MPEP and the Official Gazette Notice (dated 11-19-1996) permit a reasonable number of sequences (10) to be examined in a single application.

9. The claims in Groups 26-47 have been placed in the same class and subclass and therefore do not have separate status in the art.

10. There would be no serious burden if claims 20 and 21 were rejoined with claim 1.

11. Groups 1 and 448 should be rejoined under 35 USC 103(b).

This is not found persuasive because: as stated previously groups 1-47 are separate and distinct from each other as they comprise differing biochemical and physical entities having differing properties. Though some groups are closely related in subject matter and/or were listed in the same class/subclass, searches of the various groups would not be coextensive in scope. Additionally, while some compounds within various groups may share a common utility said common utility does not make said compounds less distinct. With regard to Applicants assertion that they are entitled to 10 nucleic acids sequences per application, current Office policy places the limit of one sequence per application. With regard to Applicant's request for rejoinder of various groups under 35 USC 103(b), said statute pertains to the non-obviousness of a biotechnological process using a novel and non-obvious composition. Said statute does not read on the election/rejoining of restricted claims. It should be noted that Applicant was correct in his assertion that claim 19 should not have been included in Group II. Said claim is drawn to a distinct entity and should have been placed in a separate group.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7-57 have been withdrawn from consideration. Claims 1-6 are currently under examination.

Claim Objections

Claims 1, 5 and 6 are objected to because of the following informalities: The abbreviation HDAg is used without defining its meaning when initially used. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites improper Markush language. It is unclear whether "a fragment thereof" refers to a fragment of a "drug" or a fragment of any of the preceding group members.

Claim 2 is rendered vague and indefinite by the use of the term "a ligand interaction peptide". It is unclear what is meant by said term. What criteria are used to determine if there is an "interaction"? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 2 is rendered vague and indefinite by the use of the term "a chemical". It is unclear what is meant by said term. What criteria are used to determine if a given substance is a "chemical"? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 2 is rendered vague and indefinite by the use of the term "an effector". It is unclear what is meant by said term. An "effector" of what? What criteria are used to determine if a given substance acts as an "effector"? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 2 is rendered vague and indefinite by the use of the term "a signal amplification peptide". It is unclear what is meant by said term. What type of signal is amplified? What criteria

are used to determine if a given peptide "amplifies" a signal? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 2 is rendered vague and indefinite by the use of the term "an enhancer recognition protein". It is unclear what is meant by said term. What type of enhancer is being recognized? What criteria are used to determine if there is "recognition"? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 2 is rendered vague and indefinite by the use of the term "a small organic molecule". It is unclear what is meant by said term. What criteria are used to determine if a molecule is "small:"? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 2 is rendered vague and indefinite by the use of the term "a test substance". It is unclear what is meant by said term. What is being tested? What role does the claimed substance play in the "test"? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 2 is rendered vague and indefinite by the use of the term "a cytotoxic agent". It is unclear what is meant by said term. Cytotoxic to what type of cell? What criteria are used to determine if an agent is "cytotoxic"? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 2 is rendered vague and indefinite by the use of the term "a substrate". It is unclear what is meant by said term. A substrate to what? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 2 is rendered vague and indefinite by the use of the term "a solid substrate". It is unclear what is meant by said term. A substrate to what? What criteria are used to determine if a given substrate is "solid"? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 3 is rendered vague and indefinite by the use of the term "binding partners". It is unclear what is meant by said term. What criteria are used to determine if two given substances are binding partners? Under what conditions? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang et al. (Journal of Virology, Vol. 66 No. 10, Oct 1992, pages 6019-6027—IDS-5).

The instant invention is drawn to a fusion protein comprising HDAg and at least one binding moiety. Said binding moiety can be an enzyme, an antigen, an antibody, a ligand, a receptor, an oligonucleotide etc. Said fusion molecule may be expressed as a single unit (claim 6).

Chang et al disclose HDAg-β-galactosidase fusion proteins (see pages 6019-6021). Said fusion proteins were expressed *in vitro* as a single unit using plasmids (see page 6021). Since β-

galactosidase is interpreted as being at least an antigen and/or a ligand and/or an enzyme and/or a chemical and/or a label, Chang et al. anticipates all the limitations of the claimed invention.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (Virology, Vol. 169, Feb 1994, pages 169-175).

The instant invention is drawn to a fusion protein comprising HDAg and at least one binding moiety. Said binding moiety can be an enzyme, an antigen, an antibody, a ligand, a receptor, an oligonucleotide etc. Said fusion molecule may be expressed as a single unit (claim 6).

Lee et al disclose GST-HDAg fusion proteins (see page 170). Said fusion proteins were expressed *in vitro* as a single unit using plasmids (see page 170). Consequently, Lee et al. anticipates all the limitations of the claimed invention.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonelli et al. (EP 0485347).

The instant invention is drawn to a fusion protein comprising HDAg and at least one binding moiety. Said binding moiety can be an enzyme, an antigen, an antibody, a ligand, a receptor, an oligonucleotide etc. Said fusion molecule may be expressed as a single unit (claim 6).

Bonelli et al disclose HDAg-β-galactosidase fusion proteins (see page 3). Said fusion proteins were expressed *in vitro* as a single unit using plasmids (see page 3, and Table 1). Consequently, Bonelli et al. anticipates all the limitations of the claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7911. The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman , Primary Examiner, can be reached on (703) 308-1032. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman
October 18, 2001